



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

FEB - 8 2007

1148 7 APR 15 2435

Mr. Shawn Sherwood  
Research and Development  
Next Proteins, Inc.  
5750 Fleet Street, Suite 100  
Carlsbad, California 92008

Dear Mr. Sherwood:

This is in response to your letter of January 15, 2007 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product **Aria Women's Protein** is the subject of claims that represent that it contains soy protein that may reduce the risk of coronary heart disease. These statements are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B) because they represent that the product will reduce the risk of a disease or health related condition (i.e., coronary heart disease). FDA has authorized a health claim about the relationship between soy protein and coronary heart disease (see 21 CFR 101.82). A dietary supplement that meets the eligibility and message requirements set forth in the regulation may bear a claim for the relationship between phytosterol/stanol esters and coronary heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.82 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.82 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary heart disease.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Vasilios Frankos". The signature is fluid and cursive, with a long horizontal stroke at the end.

Vasilios H. Frankos, Ph.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 C.F.R. § 101.93

RECEIVED  
1/29/07

This notification is being filed on behalf of Next Proteins, Inc. 5750 Fleet Street, Suite 100 Carlsbad, Ca 92008, which is the manufacturer of the product which bears the statements identified in the Notification. This Notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling statements appears is Aria® Women's Protein.

The text of the structure-function statement for which notification is now being given is:

- Statement 1: Heart Healthy  
Statement 2: Aria® Women's Protein is research proven to have a low glycemic index (GI) rating.  
Statement 3: Consuming 25g of soy protein per day, in conjunction with a diet low in saturated fat and cholesterol, may decrease the risk of coronary heart disease. A serving of Aria has 7g of soy protein.

The following summary identifies the dietary ingredient(s) for which the statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	Soy Protein Isolate
2.	Whey Protein Concentrate, Whey Protein Isolate, Soy Protein Isolate, Fructose, Calcium Phosphate, Lecithin, Soy Isoflavones, Cellulose Gum, Natural Vitamin E
3.	Soy Protein Isolate

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1-3.	Aria® Women's Protein	Label

I, Shawn Sherwood, am authorized to certify this Notification on behalf of Next Proteins, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Next Proteins, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date :

1/15/07

By:



Shawn Sherwood  
Research and Development

#1852

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